FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Tuesday, September 27, 2016 Commonwealth Conference Center Second Floor Board Room 3 Department of Health Professions Perimeter Center 9960 Mayland Drive Henrico, Virginia 23233

CALL TO ORDER:

The meeting was called to order at 9:00 a.m.

PRESIDING:

Ellen B. Shinaberry, Committee Chairperson

MEMBERS PRESENT:

Cynthia Warriner

STAFF PRESENT:

Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
Anne G. Joseph, Administrative Proceedings Division
Mykl D. Egan, Administrative Proceedings Division

Partners Pharmacy of Virginia, LLC Permit #0201004141

The purpose of the informal conference was to act upon the Application of Partners Pharmacy of Virginia, LLC for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulations. Present for the meeting from Partners Pharmacy of Virginia, LLC were Cheri Inman Luster, Pharmacist-In-Charge of Partners Pharmacy of Virginia, LLC, Shakema Poulson, Director of Partners Pharmacy of Virginia, LLC, Bill Gleason, Vice President of Cubex, and Karen Nishi, Consultant Pharmacist at Cubex

Partners Pharmacy of Virginia, LLC, requested a waiver of Regulation 18 VAC 110-20-555 (6) requiring that the drugs loaded in the device must be by a pharmacist or pharmacy technician trained in proper loading of the system.

For the purpose of this pilot program, Partners Pharmacy of Virginia is requesting approval of an innovative program to allow non-pharmacy personnel to reload the automated drug dispensing systems that are located at various nursing homes in the Commonwealth, and to use the automated drug dispensing systems as emergency and stat drug devices. Partners Pharmacy will fill the "cubies" that will be sent to the nursing homes and be loaded in to the automated dispensing devices using Cubex software by non-pharmacy personnel. In

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addition, the automated dispensing devices will be used both for stat meds as well as emergency meds and a waiver of Regulation 18VAC110-20-550 (5b) for the 20 dosage limit will be required if approved.

Upon a motion by Ms. Warriner, and duly seconded by

Ms. Shinaberry, the Committee unanimously voted to

Closed Meeting:

convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an innovative (pilot) program for Partners Pharmacy of Virginia, LLC. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, Anne G. Joseph, and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Decision:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

After consideration of the application and statements concerning the innovative (pilot) program, Ms. Shinaberry stated the Committee shall issue an order that approves the innovative (pilot) program for a period of three (3) years from the date the Order is entered by the Board with the following terms and conditions that were read by Ms. Juran:

- The innovative pilot program shall apply to two nursing homes of Partners Pharmacy's choosing.
- The Cubex system may be used for stat and emergency kit purposes.
- Partners Pharmacy shall provide evidence to the Board that it has obtained controlled substances registrations for all nursing homes it services, without an in-house pharmacy, that contain the Cubex system.
- The Cubex system may contain more than 20 solid dosage units per schedule and more than 30 ml of liquid dosage units.
- Designated nursing personnel may load the pharmacist-verified "cubies" into the automated dispensing device.

- Partners Pharmacy and the designated nursing homes shall be subject to one unannounced inspection by an inspector of the Department of Health Professions within 12 months from the date that the Board approves Partners Pharmacy's policies and procedures as set forth in Term 1(a) of this Order.
- The inspection shall be conducted during normal business hours and shall include a review of policies and procedures in the use of the Cubex system in the pilot program.
- Partners Pharmacy shall be responsible for the payment of the inspection fee, to be paid to the Board within 30 days of the inspection. Any fee not paid in a timely manner will be sent for collection. In the event that any inspection reveals a possible violation of the laws or regulations pertaining to the practice the conduct of a pharmacy in Virginia or the Virginia Drug Control Act (Virginia Code §§ 54.1-3400 et seq.), the Board may notice Partners Pharmacy to appear for an administrative proceeding.
- Partners Pharmacy may request to expand the program to additional nursing homes under the above terms and conditions 12 months after the initiation of the program. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation or modification.
- Reports of significant errors or other problems, or failure to comply with the terms and conditions described above in this Order or any statute or regulation governing the practice of pharmacy, shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

Central Virginia Training Center Pharmacy Permit #0201000997 The purpose of the informal conference was to act upon the Application of Central Virginia Training Center (CVTC) Pharmacy for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulations. Present for the meeting from Central Virginia Training Center Pharmacy was Teresa Graham, Pharmacist-In-Charge for CVTC Pharmacy.

CVTC Pharmacy requested a waiver of various sections of Regulation 18 VAC 110-20-555 as their automated dispensing device is incapable of meeting the requirements and the facility is scheduled to close in the near future. The pending closure of the facility precludes the facility's ability to purchase a new automated dispensing device.

For the purpose of this pilot program, CVTC Pharmacy is requesting the ability to use a Documed dispensing cabinet, "an older semi-computerized automatic dispensing machine" for retrieving drugs for stat box and emergency drug kit purposes when the local backup pharmacy is closed.

Upon a motion by Ms. Warriner, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for CVTC Pharmacy. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, Anne G. Joseph, and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision

After consideration of the Application and statements concerning the innovative (pilot) program, Ms. Shinaberry stated the Committee approved CVTC Pharmacy's use of a Documed machine to retrieve medications for stat box and emergency drug kit purposes under the following terms and conditions:

- Pilot program begins on date the order is entered and ends either when CVTC has closed or December 31, 2020, whichever occurs first.
- The Documed machine may be used only for stat and emergency purposes. It may not be used to store drugs for routine administration.
- Restriction in Regulation 18VAC110-20-550(5)(b) for a stat box to contain no more than

Closed Meeting:

Reconvene:

Decision:

20 solid dosage units per schedule and more than 30ml of liquid dosage units is waived.

- CVTC shall fully comply with 18VAC110-20-550 except as provided below:
 - o Requirements in Regulation 18VAC110-20-555(1) and (3) are waived.
 - requirements of of the lieu In the of 18VAC110-20-555(8) Regulations, CVTC shall conduct daily counts of all C-II through C-V controlled substances dispensed from the Documed.
 - requirements lieu of the 18VAC110-20-555(9)(c) of the Regulations, CVTC shall conduct a monthly audit of all C-II through C-V controlled substances dispensed from the Documed by comparing the medications dispensed with residents' medication administration records.
 - Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation or modification.
 - Reports of significant errors or other problems, or failure to comply with the terms and conditions described above in this Order or any statute or regulation governing the practice of pharmacy, shall constitute grounds for the recission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

ADJOURN:

With all business concluded, the meeting adjourned at 4:00 p.m.

Ellen B. Shinaberry, Committee Chairman

J. Samuel Johnson, Jr. Deputy Executive Director

/2/14/16 Date

Date